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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/599,274	06/22/2000	Karl Andrew Garrill	PG4114	7879

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EXAMINER

FOSTER, JIMMY G

ART UNIT	PAPER NUMBER
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3728

DATE MAILED: 04/22/2002

16

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/599,274

Applicant(s)
Garrill et al.

Examiner
Jimmy G. Foster

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3728



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Mar 8, 2002
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 12
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____

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1. The allowance of claims 1-16 is hereby withdrawn in view of the following new grounds of rejection of the claims.

2. The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1, 2, 5, 6, 10 and 11 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Alband (5,775,321) in view of Cullen (3,371,825). The reference of Alband substantially discloses an inhalation device that includes an HFA propellant combined with an ethanol and a medicament/drug product.

The reference of Cullen, at column 1, lines 24-34, column 1, lines 45-55, and col. 2, lines 3-5, suggests that when a hydrocarbon propellant for packaged medicaments/drugs is combined with an inadvertent water content, as which is present with alcohols, an undesirable acid such as hydrofluoric acid is formed, and a breakdown of the propellant occurs. The reference of Cullen further suggests that a moisture absorbing material placed with the propellant of an aerosol medical discharge device would be desirable in order to prevent this propellant

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breakdown. One example of an absorbent/desiccant that can be used is silica gel.

Accordingly, it would have been obvious in view of Cullen to have provided a moisture absorbent with the propellant of the device of Alband in order to prevent propellant breakdown.

Regarding claim 10 of Applicant, the absorbent getter 55 taught by Cullen is a large granule so that it will not foul the dispensing orifice for the propellant. It has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. *Suggests that. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8. Although Cullen suggests one such granule, it would have been obvious, as being a mere duplication of structure and function to have provided more than one such granule if one desired to provide a greater capacity of moisture absorption.

4. Claims 7-9 are rejected under 35 U.S.C. § 103 as being unpatentable over the references as applied to claim 6 above, and further in view of Shichman et al (5,322,161). The reference of Shichman et al, at column 2, lines 21-34, suggests that it is common practice to contain a packaged absorbent (e.g. silica gel) in its own nylon mesh pouch when an absorbent is packaged with content where it is desired to reduce moisture contamination of the packaged product. Apparently, this would prevent uncontrolled movement of the absorbent per se in the package with respect to the packaged product. The pouch taught

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pouch may either be loose or attached directly to the package structure. Accordingly, it would have been obvious in view of Shichman et al to have provided the absorbent material of Cullen, as applied above to the delivery device of Alband, in a nylon mesh bag (for the absorbent) for the purpose of preventing uncontrolled movement of the absorbent material with respect to the propellant and drug of Alband, wherein the pouch is loose or attached to the delivery apparatus.

5. Claims 3, 4 and 12-16 are rejected under 35 U.S.C. § 103 as being unpatentable over the references as applied to claim 1 or 11 above, and further in view of official notice taken by the examiner that the drug products claimed in claims 3 and 12-16, and their intended effect as medication for the human body, are known and are prior art.

To have used the absorbent and inhaler combination obvious from Alband and Cullen, as indicated above, for any particular known medicament/drug, such as those recited in Applicant's claims 3 and 12-16, would have further been obvious in order to provide metered drug delivery of such a drug to the human body.

6. For contacting the PTO by phone, the following contact numbers may be used:

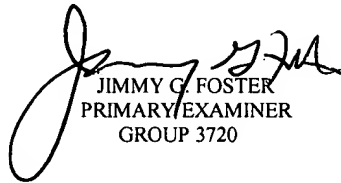
- For tracking of papers and association of papers with cases --
Customer Service. . . (703)306-5648
- For matters regarding examination -- Examiner:
Jim Foster (703)308-1505
- For faxing of correspondence:
 - Draft amendments only-(703)308-7769
(Examiner should be notified of fax)
 - Formal correspondence-(703)305-3579 or 305-3580
 - RIGHT FAX-Before Final . . (703) 872-9302
 - After Final . . . (703) 872-9303
- (The examiner ordinarily will not retrieve formal correspondence)
- For petitions:
 - Before the Examiner . (703)308-1505

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Before the Director . (703) 308-3872
Other petitions . . . (703) 305-9282



JIMMY G. FOSTER
PRIMARY EXAMINER
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JGF
April 16, 2002